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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/722,184

11/25/2003

Jeffrey O. Phillips

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08/06/2008

MAYER BROWN LLP  
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EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

08/06/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/722,184	<b>Applicant(s)</b> PHILLIPS, JEFFREY O.	
	<b>Examiner</b> Celia Chang	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 151-153, 156, 160, 161, 167-170 and 174-210 is/are pending in the application.
- 4a) Of the above claim(s) 158, 171-173 and 211-272 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 151-153, 156, 160, 161, 167-170 and 174-210 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/16/04, 3/4/05, 9/9/05, 5/26/06, 10/31/07, 11/12/07, 4/17/08, 5/21/08.

### DETAILED ACTION

1. Amendment and response filed by applicants dated May 1, 2008 have been entered and considered carefully.

Claims 151-153,156,160,161,167-170 and 174-210 are pending. Claims 158,171-173 and 211-272 stayed withdrawn from consideration.

2. The rejection of claim 152 under 35 USC 112 2<sup>nd</sup> paragraph is dropped in view of the amendment of the claim.

3. The rejection of claims 151-153,156,160-161,167-170,174-210 under 35 USC 112 first paragraph is maintained for reason of record.

Applicants argued that it was disclosed in the specification that the lower limit of the buffering range is calculated as the pKa of a given proton pump inhibitor +0.7 log values. Therefore, one skilled in the art can modify the ranges of the examples using bicarbonate to achieve this pKa+0.7 log requirement.

It is noted that on p.111 of the specification, it was clearly disclosed that "...the solubilities of the buffers and proton pump inhibiting agents are important considerations because solubility is a key determinant of the rate of interaction of H<sup>+</sup> ion with another compound". Therefore, the "composition" when choosing any other buffering agent which has a different solubility from the bicarbonate, although the quantities can be calculated or modified from the bicarbonate examples, such quantitative relationship between another buffer (other than sodium bicarbonate) would be different from 0.2-5mEq. The two examples as explained by applicants on pages 134-138 have pKa values as bicarbonate=6.14, dibasic phosphate=7.12. While the buffering agent of claim 161, for example acetate, would have pKa about 3, therefore, the "quantity" equivalent to the effect of 0.2-5mEq of bicarbonate would be quite different from dibasic phosphate. There is no evidence that all the specific buffers as named in claim 161 would have sufficiently same pK values and solubility as the sodium bicarbonate to render that all operable ranges for the named buffer would be within the same 0.2-5 mEq per 2 mg omeprazole range.

4. The rejections of claims 151-153, 156, 160-161, 167-170 and 174-210 are rejected as being unpatentable over claims 18-56 of US 6,489,364 or claims 1-51 of US 6,699,885 or over the copending claims 24-25, 32-36, 77-88, 90-100, 103-110 of SN10/641,732, (all of record) on the ground of nonstatutory obviousness-type double patenting are maintained for reason of record since no terminal disclaimer has been filed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*July 30, 2008*

*/Celia Chang/*  
*Primary Examiner*  
*Art Unit 1625*